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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/773,911 | 02/06/2004 | Min-Hao Kuo | MSU-08548 | 8594 |

7590 12/27/2005

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EXAMINER

JOIKE, MICHELE K

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1636

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/773,911 | Applicant(s) KUO, MIN-HAO | |
| | Examiner Michele K. Joike, Ph.D. | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/06/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT.Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12 and 21 are drawn to a fusion protein, classified in class 530, subclass 350.
- II. Claims 13-16, drawn to DNA encoding the fusion protein, classified in class 435, subclass 320.1, for example.
- III. Claims 17-20, 24-25, drawn to the method for detecting protein-protein interactions, classified in class 530, subclass 387.9.
- IV - XXII. Claim 22, drawn to nucleotide sequences SEQ ID NOs: 1-14, 29, 31, 33, 35, 37, classified in class 536, subclass 23.1.
- XXIII- XLI. Claim 23, drawn to amino acid sequences SEQ ID NOs: 15-28, 30, 32, 34, 36, 38, classified in class 530, subclass 350.
- XLII. Claims 21, 26-29, drawn to a compound containing a protein kinase, classified in class 530, subclass 352.

The inventions are distinct, each from each other for the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise amino acid sequences (Group I) vs.

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nucleic acid sequences (Group II). Polypeptides are biochemically, functionally and structurally unrelated to nucleic acid sequences. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Inventions I, II, XLII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Groups I and XLII and the nucleic acids of Group II are related to the process of use recited in Group III. However, the proteins of Group I can be used to raise antibodies against histone acetyltransferases or protein kinases so as to identify these enzymes in samples and the nucleic acids of Group II can be used as probes to identify corresponding sequences in samples.

Inventions IV-XXII and XXIII-XLI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve nucleic acid sequences (Groups IV-XXII) vs. amino acid sequences (Groups XXIII-XLI) with each nucleic acid sequence distinct and unrelated (in sequence) from every other nucleic acid sequence and each protein sequence distinct and unrelated (in sequence) from every other

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protein sequence. Each nucleic acid sequence is patentably distinct from each protein sequence in that polypeptides are biochemically, functionally and structurally unrelated to nucleic acid sequences. A search of one would not be co-extensive with a search of the other and hence would be burdensome.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims IV-XXII and XXIII-XLI are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: in the instant case, the claims are related because all of the groups contain nucleotide sequences, however, each group involves products not required by the other so that groups are not linked by a single feature. Distinctly different nucleotide sequences are structurally distinct chemical compounds and are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences.

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In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence, therefore one group from the Groups listed above.

Inventions I, II, IV-XXII, XXIII-XLI and XLII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve nucleic acids and proteins wherein the proteins are structurally and functionally unrelated to the nucleic acid sequences. Each specific nucleic acid sequence is distinct from each of the other nucleic acid sequences and each of the protein sequences is structurally and functionally distinct from the other protein sequences.

Inventions III and IV-XXII, XXIII-XLI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the claimed method of detecting protein-protein interactions does not require the specific nucleic acid or protein sequences claimed in Groups IV-XXII or XXIII-XLI and can be practiced without said sequences. The sequences could be used in different methods than the method recited in Group III, such as probes for detecting the presence of related sequences in samples.

Claim 21 link(s) inventions I and XLII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joiike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on 8:00-5:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER